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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/731,749 | 12/09/2003 | Robert P. Kimberly | UAB-14303/22 | 4297 |

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| EXAMINER | |
|---|---|
| KETTER, JAMES S | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1636 | |

DATE MAILED: 06/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/731,749 | KIMBERLY, ROBERT P. | |
| | Examiner | Art Unit | |
| | James S. Ketter | 1636 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/9/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The disclosure is objected to because of the following informalities: At the paragraph bridging pages 4 and 5, there appears the parenthetical phrase "(Please fill in reference prop #110, now 1)". Clearly, this artifact is unintentional and potentially confusing.

Appropriate correction is required.

Claim 1 is objected to because of the following informalities: Claim 1 as filed depends from a higher numbered claim. Appropriate correction is required.

Claim 12 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 11, from which claim 12 depends, is limited to the single nucleotide polymorphism at codon 1969. Claim 12, however, appears to encompass any codon encoding alanine or threonine, an is thus broader than claim 11.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10 and 13-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the

relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discloses only a single position at which CR1 varies, i.e., nucleotide 5932. No polymorphism is disclosed for CR2. The only polymorphisms which would function as disclosed in the present invention are those actually present in the population of patients. However, the presence of such polymorphisms (i.e., the structures of all of the genes in a population) cannot be predicted based solely on the function as a molecular marker, even where there is an associated phenotypic variation, as no theory or algorithm is or was sufficiently developed to predict the change in function of a protein based upon primary sequence changes, i.e., a structural change. Stated otherwise, there was not known from the specification or the art a structure-function relationship which would have permitted knowing the presence or identity of a polymorphism based either upon mere phenotypic variation, or based upon no a priori knowledge at all. As such, one of skill in the art would not have recognized that Applicant had possession of the full scope of the instant claims at the time of filing.

Claims 14 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims are drawn to a use of (which might be understood to be a method of using) a single nucleotide polymorphism in a complement receptor to identify individual

susceptibility to a disease. However, claims 14 and 15 encompass any possible polymorphism. There is no disclosure of what the results of such a method for any given disease and any given polymorphism would mean, i.e., there is no description of determining susceptibility to a disease from the data thus generated. As such, one of skill in the art would not have recognized that Applicant had possession of the full scope of the instant claims at the time of filing.

Claims 14 and 16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims are drawn to a use of (which might be understood to be a method of using) a single nucleotide polymorphism in a complement receptor to identify individual susceptibility to a disease. However, claims 14 and 16 encompass any possible diseases. There is no disclosure of what the results of such a method for any given disease and any given polymorphism would mean, i.e., there is no description of determining susceptibility to a disease from the data thus generated. As such, one of skill in the art would not have recognized that Applicant had possession of the full scope of the instant claims at the time of filing.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14-16 provide for the use of a single nucleotide polymorphism, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 14-16 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claims 1-13 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 recites 'said complement receptor gene". However, there is insufficient antecedent basis for this phrase.

Claim 1 recites the phrase "polymorph which is predominant in humans." However, it is not clear what "predominant" means, as there are two different complement receptor genes in use in claims 4 and 5, i.e., the cell and the second cell.

Claims 2 and 4, and therefore 3 and 5-13 which depend therefrom, recite in the preambles, that they are drawn to methods of "correlating the ability of a cell to bind a complement component and cellular susceptibility to a disease". However, there is no step or limitation in the claim in which a disease state is assessed, and therefore it is not clear in what manner or by what types of process steps such a correlation might be made, or even whether such a step must be included in the claimed method. As such, the metes and bounds of the instant invention cannot be determined.

Claim 16 recites codon 1969, but fails to recite in which gene said codon is found. As there are many genes in the art shorter than 1969 codons, the claim is not merely broad, but confusing as well.

Any inquiry concerning this communication or earlier communications from the Examiner with respect to the examination on the merits should be directed to James Ketter whose telephone number is (571) 272-0770. The Examiner normally can be reached on M-F (9:00-6:30), with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Remy Yucel, can be reached at (571) 272-0781.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Jsk
June 10, 2005

JAMES KETTER
PRIMARY EXAMINER